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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,571	06/04/2001	Gene W. Kammerer	GYN-0090	4207
27777	7590	10/03/2005		
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER LACYK, JOHN P	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/873,571

Applicant(s)

KAMMERER ET AL.

Examiner

John P. Lacyk

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/13/04</u> . | 6) <input type="checkbox"/> Other: ____ |

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1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of copending Application No. 10/191,572. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are an obvious change in the scope of the invention, one claim merely uses means language for claiming the same element as in the other claim and therefore are not patentably distinct from one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claim 2 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of copending Application No. 10/191,572. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are an obvious change in the

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scope of the invention, both claiming a mesh, a curved needle element and coupling means or coupling element for connecting the mesh to the needle.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claim 2 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 20 of U.S. Patent No. 6,273,852. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims both claim a surgical instrument for treating incontinence having a mesh or tape having connecting means and a curved needle element having an attaching means or coupling means for connecting the end of the needle to the mesh or tape. The claims claim the same device using slightly different language and are not patentably distinct from each other.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Staskin et al article (The Gore-tex sling procedure for female sphincteric incontinence: indications, technique, and results).

Staskin et al discloses a Gore-tex patch that is constructed into a sling (page 296) which uses a suture secured to the lateral edge of the graft on each side that is considered to be the first and second coupling means. A single tipped ligature carrier (curved needle element) is connected by passing the suture through the eyelet (needle coupling means) of the ligature carrier.

7. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Norris et al article (Use of Synthetic Material in Sling Surgery: A Minimally Invasive Approach). Norris et al teaches a Gore-tex sling having a "coupling means" or suture along the edges of the sling (see Figure 2). The suture carrier (curved needle element in Figure 3) has an eyelet (needle coupling means) that passes the suture (first and second mesh coupling means) through to connect the carrier and the sling.

8. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by O'Donnell (Combined Raz Urethral Suspension and McGuire Pubovaginal Sling For Treatment of Complicated Stress Urinary Incontinence).

O'Donnell teaches a mesh (fascial sling) having sutures at both ends (first and second mesh coupling means, Figure 4) and a curved needle with an eyelet (needle coupling means) to attach to the suture.

9. Claim 2 is rejected under 35 U.S.C. 102(e) as being anticipated by Claren et al (5,899,909).


Claren et al discloses (column 4, lines 30-65) a mesh (tape) 26 for implanting into the lower abdomen configured to be attached to a shrink hose (first and second mesh coupling means) and a curved needle element having a shoulder 33 (needle coupling means) for attaching to the shrink hose.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Lacyk whose telephone number is 571-272-4728. The examiner can normally be reached on Mon-Fri, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John P Lacyk
Primary Examiner
Art Unit 3736

J.P. Lacyk